

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

ARBOR PHARMACEUTICALS LLC,

Plaintiff,

v.

ANI PHARMACEUTICALS, INC.

Defendant.

CASE NO.: 01:17-cv-04910-DWF-LIB

Jury Trial Demanded

DEFENDANT'S STATEMENT OF THE CASE

ANI Pharmaceuticals, Inc. ("ANI") submits this Statement of the Case in compliance with the Court's February 15, 2018 Pretrial Conference Notice and Order.

I. CONCISE STATEMENT OF ANI'S VERSION OF THE FACTS AND SUMMARY OF THE FACTS WHICH SUPPORT ITS CLAIMS AND DEFENSES

ANI owns ANDA 062055 (the "ANI ANDA") for Erythromycin Ethylsuccinate for Oral Suspension USP, 200 mg/5ML (the "EES Product" or "ANI's Product"). The ANI ANDA was originally approved on November 27, 1978, for Barr Pharmaceuticals Inc. ("Barr"). This ANDA was "discontinued" in 2003 after Barr ceased marketing the product. Notably, "discontinued" refers to the marketing status of the drug product offered under the ANDA, not the approval status of the ANDA. Products listed as

"discontinued" by the FDA are "approved products that have never been marketed [or] have been discontinued from marketing...." As such, products listed as "discontinued" may nevertheless be reintroduced to the marketplace under the previously approved ANDA. In 2015, ANI purchased the ANDA and has taken the necessary steps to launch the EES Product pursuant thereto.

In its Complaint, Arbor asserts claims for false advertising and unfair competition under the Lanham Act (Counts I and II) and related claims under state and common law (Counts III–VI). All of Arbor's asserted claims are based upon the unsupported and conclusory allegations that ANI's EES Product is an "unapproved" drug product that is not "AB-rated" to, and therefore is not a generic substitute for, Arbor's branded EES products. As Arbor acknowledges in its Complaint, ANI holds an approved ANDA for its EES product. Arbor may not circumvent the FDA's exclusive regulatory and enforcement authority by seeking to assert that ANI's EES Product violates the FDCA, when the FDA has not reached that conclusion. Further, ANI denies that its marketing and promotion of ANI's EES Product is false or misleading as it is the owner of an approved ANDA, and is not marketing ANI's EES Product in a false or misleading manner. Arbor reserves the right to supplement its contents as discovery progresses.

II. ITEMIZATION AND EXPLANATION OF CLAIMED DAMAGES

ANI has not asserted an affirmative claim for damages as its motion to dismiss is still pending, and ANI has not answered or counterclaimed in this case. ANI denies that Arbor is entitled to damages or other relief.

Dated: 03/19/2018

s/Sarah M. Stensland

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**ATTORNEYS FOR DEFENDANT
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CERTIFICATE OF SERVICE

I certify that, on this 19th day of March, 2018, a copy of the foregoing Defendant's Statement of the Case has been filed electronically and is available for viewing and downloading from the Court's ECF system. Notice of filing will be sent by e-mail to all parties of record by operation of the Court's ECF system and service is being made on all parties through the Court's ECF system.

Dated: March 19, 2018

By: s/ _____

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